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Appln. 11-504890

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**Specification**

**1. Title of the Invention**

Method for producing an orthodontic mouthpiece

**2. Claims**

1. A method for producing an orthodontic mouthpiece, by which a dentition plaster cast taken from a patient having a malaligned dentition is modified to produce an orthodontic plaster cast, a softened thermoplastic polymer sheet is adhered to the orthodontic plaster cast, and then the softened thermoplastic polymer sheet is solidified and removed.

2. A method for producing an orthodontic mouthpiece according to claim 1, wherein the thermoplastic polymer has a flexure elasticity (ASTM-D747) of 800 kg/cm<sup>2</sup> or less.

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**3. Detailed Description of the Invention**  
**[Background of the Invention]**

**<Field of the Invention>**

The present invention relates to a method for producing an orthodontic mouthpiece for easily performing orthodontic treatment without damaging the teeth.

**<Prior Art>**

Conventionally, for orthodontic treatment, a method for attaching a tool for wiring normal teeth in order to apply a force to a tooth to be orthodontically-treated is generally used.

**<Problems to be Solved by the Invention>**

Such a method has problems in that the other normal teeth are likely to be damaged and the patient feels a pain in the wired teeth since a force is likely to be applied to a part of the teeth that are wired.

**[Overview of the Invention]**

**<Summary>**

The present inventors accumulated active studies in order to solve the above-described problems. As a result, the present inventors obtained the following knowledge and completed the present invention. By using a special mouthpiece which is completely different from that of conventional orthodontic methods, orthodontic treatment can be easily performed unlike conventional orthodontic

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methods. With the special mouthpiece, the force to be applied to the tooth to be orthodontically-treated can be held by all the teeth without damaging the other normal teeth, and the force can be especially applied only to the tooth to be orthodontically-treated.

According to the method for producing an orthodontic mouthpiece of the present invention, a dentition plaster cast taken from a patient having a malaligned dentition is modified to produce an orthodontic plaster cast, a softened thermoplastic polymer sheet is adhered to the orthodontic plaster cast, and the softened thermoplastic polymer sheet is solidified and removed.

<Effect>

The orthodontic mouthpiece produced by the method according to the present invention provides the following significant effects: the mouthpiece is formed of a soft material and thus is easily attached; the mouthpiece is applied to all the teeth and thus does not cause pain to a specific tooth; and in addition, the mouthpiece can be easily removed for washing the teeth and the palate.

[Specific Description of the Invention]

[I] Production of an orthodontic plaster cast

(1) Production process of a dentition model of a patient

According to a method for producing an orthodontic mouthpiece of the present invention, a concave dentition

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model is first produced from the palate of the patient for the orthodontic treatment using an impression material, and plaster is poured into the concave dentition model. Thus, an accurate convex dentition plaster cast of the patient is produced.

For producing the concave dentition model, any impression material generally used in dentistry is usable. For example, silicone impression materials, agar impression materials, and arginate impression materials are used. For the convex dentition plaster cast, it is preferable to use plaster, hard plaster or super-hard plaster.

(2) Production process of an orthodontic plaster cast

The convex dentition plaster cast of the patient produced by the above-mentioned method is used as a base and is modified into a final form or into an intermediate form to be further modified. Thus, an orthodontic plaster cast is produced.

The convex dentition plaster cast of the patient is modified to produce such an orthodontic plaster cast as follows: A portion to which a correcting force is not to be placed is bulged; and plaster is cut off from a portion on the opposite side, i.e., the portion to which a correcting force is to be placed.

For cutting, any tool which can cut plaster is usable. Generally, a bar or a hand piece used by dental technicians is used. For bulging, a composite resin, an

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epoxy resin or the like is used. For bulging, any material which has sufficient adhesive strength and tensile strength for withstanding the subsequent operations is usable.

[II] Production of an orthodontic mouthpiece

(1) Thermal molding of a thermoplastic polymer sheet

A thermoplastic polymer sheet which has been softened by heating is adhered to the orthodontic plaster cast produced by the above-described method, and more closely adhered thereto by thermal molding to accurately transfer the dentition of the orthodontic plaster cast.

The thermoplastic polymer used here needs to be superb in elastomer characteristics and in strength and also should be easily attachable.

In order to fulfill these conditions, the thermoplastic polymer used desirably has a flexure elasticity of 800 kg/cm<sup>2</sup> (ATSM D747) or less, preferably 50 to 500 kg/cm<sup>2</sup>.

Materials fulfilling such conditions are: ethylene-based resins such as, for example, ethylene-vinyl acetate copolymer, ethylene acrylic acid ester copolymer, ethylene methacrylic acid ester copolymer, ethylene- $\alpha$ -olefin copolymer, and polyethylene; ethylene-propylene elastomer; ethylene-propylene-diene compound-based elastomer; styrene-butadiene-based elastomer (including materials with water added thereto); polyester

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elastomer; urethane elastomer, polybutadiene; and the like.

Among these materials, it is preferable to use ethylene-based resins (especially, ethylene-vinyl acetate copolymer, ethylene- $\alpha$ -olefin copolymer, polyethylene) or styrene-butadiene-based elastomer.

These materials may be used independently, or mixed or laminated with other polymers. Various additives may also be used.

Such additives include, for example, pigments, anti-aging agents, agents to enhance the molding, stabilizers, ultraviolet-preventive agents, anti-oxidants, and abrasion-preventive agents.

The thickness of the thermoplastic polymer sheet is generally 0.25 to 3 mm, preferably 0.3 to 1.5 mm, and especially preferably 0.3 to 1 mm.

Preferable specific thermal molding methods include vacuum molding and air pressure molding, but blow molding and slash molding may also be used.

The conditions for the thermal molding vary in accordance with the method of thermal molding and the type of thermoplastic polymer.

In the case where the preferable vacuum molding or air pressure molding is used, it is necessary to soften

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the thermoplastic polymer sheet. Therefore, the sheet is heated to a temperature which is higher than or equal to the vicat softening point (JIS-K7206) of the material forming the sheet and lower than or equal to the melting point of the material forming the sheet.

The thermoplastic polymer sheet having the orthodontically-treated dentition shape accurately transferred thereon by the above-described thermal molding is cooled to room temperature or to the vicinity thereof and solidified. The sheet is removed from the dentition plaster cast. The sheet is cut along the gum line and properly shaped. Thus, a concave orthodontic mouthpiece is obtained. The sheet may be cut along about 3 mm inner to or outer to the gum line, but it is preferable that the cutting line is not in direct contact with the gum line.

In the concave orthodontic mouthpiece produced in this way, only the teeth to be orthodontically-treated are difficult to fit. However, the mouthpiece has a rubber elasticity of about 50 to 800 and is not very hard, and therefore is easily attachable to the dentition of the patient. The portions other than the tooth to be orthodontically-treated are easily fit to the respective teeth. Thus, the force to be applied to the tooth to be orthodontically-treated can be dispersed and received by all the teeth.

The mouthpiece does not have a very high hardness, and thus does not damage the orthodontic plaster cast.



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Therefore, a plurality of orthodontic mouthpieces of the same shape can be produced. It is also possible to perform the next orthodontic process, using such an orthodontic plaster cast as a base, by further modifying the cast with cutting and bulging. Such an operation can be repeated a plurality of times for straightening teeth into more normal dentition.

[Experimental examples]

The orthodontic mouthpiece according to the present invention will be more specifically described by way of experiments of examples and comparative examples.

Example 1

Production of a dentition plaster cast

An impression of a patient with malaligned dentition, whose two upper front teeth are to be orthodontically-treated, was produced using an alginate impression material (Starmix, produced by Nihon Shiken Corporation). Hard plaster (Diastone, produced by Mitsubishi Kogyo Cement Kabushiki Kaisha) was poured into the impression. Thus, a dentition plaster cast was produced.

Production of an orthodontic plaster cast

The upper front teeth of the dentition plaster cast were cut off by a thickness of 1 mm using a bar used by dental technicians, and a portion opposite to the portion which has been cut off was bulged by a thickness of 1 mm with an epoxy resin-based adhesive (Konishi Bond,

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produced by Konishi Co., Ltd.). Thus, an orthodontic plaster cast was produced.

Production of a thermoplastic polymer sheet

A pressed sheet having a thickness of 0.5 mm, a length of 15 cm and a width of 15 cm of an ethylene-vinyl acetate copolymer resin (Mitsubishi Polyethy-EVA "V501H", Mitsubishi Yuka Kabushiki Kaisha; flexure elasticity: 400 kg/cm<sup>2</sup>, vicat softening point: 54°C, melting point: 91°C) was placed on an absorptive precision pressure-contact device (Starback, produced by Mitsugane Kogyo Kabushiki Kaisha). When the pressed sheet was heated to a temperature of 85°C, the pressed sheet was adhered to the orthodontic plaster cast for transference.

The transferred molded body obtained by the above-mentioned transference and molding was cooled for 5 minutes by cool air from a dryer and solidified. The transferred molded body was easily removed from the plaster cast.

Production of a mouthpiece

The transferred molded body having a concave portion 2 and a convex portion 3 was cut along a line 2 mm away from the gum line of the orthodontic plaster cast by scissors. Thus, as shown in Figure 1, an orthodontic mouthpiece 1 including an upper dentition orthodontic mouthpiece 1a and a lower dentition orthodontic mouthpiece 1b, which can be separately attached to the upper teeth and the lower teeth, was

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produced. The orthodontic mouthpiece 1 was tested for the above-mentioned patient with malaligned dentition for orthodontic treatment, such that the concave portion 2 covers the patient's dentition. The orthodontic mouthpiece 1 was easily attached, and the correcting force of a portion 4 covering the surface of the dentition was applied to the two front teeth.

After the patient with malaligned dentition wore the orthodontic mouthpiece for 1 month, the orthodontic mouthpiece was removed. The orthodontic plaster cast was modified by cutting it off by another 1 mm and bulging the opposite portion by 1 mm. Thus, a second stage orthodontic plaster cast was produced.

The second stage orthodontic plaster cast was used as a base, and another thermoplastic polymer sheet was adhered thereto. Thus, a second stage orthodontic mouthpiece was produced.

The second stage orthodontic mouthpiece was tested to the patient with malaligned dentition who had finished the first stage orthodontic treatment. The second stage orthodontic mouthpiece was attachable. This indicates that the first stage orthodontic treatment was fully performed, and that the patient was now in the second stage of orthodontic treatment.

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## 4. Brief Description of the Drawings

Figure 1 represents a perspective view of an orthodontic mouthpiece according to an example of the present invention.

1 ... orthodontic mouthpiece; 1a ... upper dentition orthodontic mouthpiece; 1b ... lower dentition orthodontic mouthpiece; 2 ... concave portion; 3 ... convex portion; 4 ... portion covering the surface of the dentition; 5 ... portion covering the surface of gums.

Fig. 1

